

Corrie J. Yackulic, WSBA No. 16063
CORRIE YACKULIC LAW FIRM PLLC
110 Prefontaine Place South, Suite 304
Seattle, Washington 98104
Tel. 206.787.1915
Fax. 206.299.9725
Corrie@cjylaw.com

**UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON**

ANNETTE HOPKINS,

Plaintiff,

vs.

ETHICON, INC. AND JOHNSON &
JOHNSON,

Defendants.

Case No.:

COMPLAINT WITH JURY DEMAND

I. CIVIL ACTION COMPLAINT

Plaintiff, ANNETTE HOPKINS (“Plaintiff”), by and through her counsel, brings this Complaint against Defendants ETHICON, INC., and JOHNSON & JOHNSON (collectively, “Defendants”, as the context may require) for injuries suffered as a result of defective pelvic mesh products designed, manufactured and marketed by Defendants, and implanted in Plaintiff. In support, Plaintiff states and avers as follows:

II. PARTIES

1. Plaintiff ANNETTE HOPKINS is, and was, at all relevant times, a resident of the state of Washington.

2. Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

1 3. Defendant, Ethicon, Inc. is a wholly owned subsidiary of Defendant Johnson
2 & Johnson and is incorporated in the state of New Jersey with its principal place of business
3 in Somerville, New Jersey.

4 4. Defendants ETHICON, INC. and JOHNSON & JOHNSON share many of the
5 same officers, directors and operations; and maintain ownership in the assets and/or liabilities
6 relating to the design, manufacture, marketing, distribution and sale of the medical device
7 line at issue in this litigation and shall be referenced collectively hereinafter as “Defendants”.

8 5. All acts and omissions of each Defendant as described herein were done by
9 its agents, servants, employees and/or owners, acting in the course and scope of their
10 respective agencies, services, employments and/or ownership.

11
12
13 **III. JURISDICTION AND VENUE**

14 6. Damages sought in this matter are in excess of \$75,000.00. Subject matter
15 jurisdiction is proper pursuant to 28 U.S.C. § 1332.

16 7. This Court has subject matter jurisdiction over the parties pursuant to 28
17 U.S.C. § 1332(a) because the parties are citizens of different states and the amount in
18 controversy exceeds \$75,000.00, exclusive of interest and costs.

19 8. Venue is proper in the Western District Court of Washington pursuant to 28
20 U.S.C. § 1391 because a substantial part of the events giving rise to this claim occurred in
21 this district.

22 9. Defendants conducted substantial business in the State of Washington and in
23 this District, distribute Pelvic Mesh Products in this District, receive substantial
24 compensation and profits from sales of Pelvic Mesh Products in this District, and made
25 material omissions and misrepresentations and breaches of warranties in this District so as to

1 subject them to *in personam* jurisdiction in this District.

2 10. Defendants conducted business in the State of Washington through sales
3 representatives and because Defendants were engaged in testing, developing, manufacturing,
4 labeling, marketing, distributing, promotion and/or selling, either directly or indirectly,
5 and/or through third parties or related entities, Pelvic Mesh Products in the State of
6 Washington; thus, there exists a sufficient nexus between Defendants' forum contacts and
7 the Plaintiff's claims to justify assertion of jurisdiction in Washington.
8

9 11. Consistent with the Due Process Clause of the Fifth and Fourteenth
10 Amendments, this Court has *in personam* jurisdiction over Defendants, because Defendants
11 are present in the State of Washington such that requiring an appearance does not offend
12 traditional notions of fair play and substantial justice.
13

14 **IV. DEFENDANTS' PELVIC MESH PRODUCTS**

15 12. In or about October, 2002, the Defendants began to market and sell a product
16 known as Gynemesh, for the treatment of medical conditions in the female pelvis, primarily
17 pelvic organ prolapse and stress urinary incontinence. All references to Gynemesh include
18 all variations of or names used for Gynemesh, including but not limited to Gynemesh PS.
19

20 13. Gynemesh was derived from a product known as Prolene Mesh, which was
21 used in the treatment of medical conditions in the female pelvis, primarily pelvic organ
22 prolapse and stress urinary incontinence. Prolene Mesh was derived from Defendants'
23 prolene mesh hernia product, and was and is utilized in the treatment of medical conditions
24 in the female pelvis, primarily pelvic organ prolapse and stress urinary incontinence. All
25 references to Prolene Mesh include all variations of Prolene Mesh, including but not limited
26 to Prolene Soft Mesh.
27
28

1 14. In or about September, 2005, the Defendants began to market and sell a
2 product known as Prolift, for the treatment of medical conditions in the female pelvis,
3 primarily pelvic organ prolapse and stress urinary incontinence. The Prolift was and is offered
4 as an anterior, posterior, or total repair system, and all references to the Prolift include by
5 reference all variations.
6

7 15. In or about May, 2008, the Defendants began to market and sell a product
8 known as Prolift+M, for the treatment of medical conditions in the female pelvis, primarily
9 pelvic organ prolapse and stress urinary incontinence. The Prolift+M was and is offered as
10 an anterior, posterior, or total repair system, and all references to the Prolift+M include by
11 reference all variations.
12

13 16. The Defendants market and sell a product known as TVT, for the treatment of
14 stress urinary incontinence in females. The TVT has been and is offered in multiple variations
15 including, but not limited to, the TVT, TVT-O, and TVT-S, and all references to the TVT
16 include by reference all variations.
17

18 17. The products known as Prolene Mesh, Gynemesh, Prolift, Prolift+M, and
19 TVT, as well as any as yet unidentified pelvic mesh products designed and sold for similar
20 purposes, inclusive of the instruments and procedures for implantation, are collectively
21 referenced herein as Defendants' Pelvic Mesh Products or the Pelvic Mesh Products.
22

23 18. Defendants' Pelvic Mesh Products were designed, patented, manufactured,
24 labeled, marketed, and sold and distributed by the Defendants, at all times relevant herein.
25

26 V. FACTUAL BACKGROUND

27 19. On November 9, 2007, Plaintiff was implanted with an Ethicon/Johnson &
28 Johnson TVT-S ("Pelvic Mesh Products", "Pelvic Mesh Product", and/or "Product") during

1 surgery performed at Providence Regional Medical Center in Everett, Washington.

2 20. The Pelvic Mesh Product was implanted in Plaintiff to treat her stress urinary
3 incontinence, the use for which the Pelvic Mesh Products were designed, marketed and sold.

4
5 21. On August 17, 2017, Plaintiff underwent revision surgery of the
6 Ethicon/Johnson & Johnson TVT-S product at Providence Regional Medical Center Everett-
7 Colby in Everett, Washington. The revision surgery was necessary because the TVT-S had
8 eroded and become exposed causing Plaintiff to suffer from pelvic and abdominal pain,
9 dyspareunia, and intermittent bleeding.

10
11 22. On January 23, 2020, Plaintiff underwent a second revision surgery of the
12 TVT-S product at Providence Regional Medical Center in Everett, Washington. Because the
13 TVT-S device could not be fully removed during her first revision, the TVT-S product again
14 eroded and became exposed causing Plaintiff to suffer from pain with daily activities and
15 dyspareunia.

16
17 23. As a result of having the Product implanted in her, Plaintiff has experienced
18 significant mental and physical pain and suffering, has sustained permanent injury and
19 permanent and substantial physical deformity and has suffered financial or economic loss,
20 including, but not limited to, obligations for medical services and expenses.

21
22 24. Additionally, Plaintiff is likely to continue to suffer from pain and
23 complication related to the TVT-S product that will require further medical intervention in
24 the future.

25 25. Defendants' Pelvic Mesh Product has been and continues to be marketed to
26 the medical community and to patients as a safe, effective, reliable, medical device; implanted
27 by safe and effective, minimally invasive surgical techniques for the treatment of medical
28

1 conditions, primarily pelvic organ prolapse and stress urinary incontinence, and as safer and
2 more effective as compared to the traditional products and procedures for treatment, and other
3 competing pelvic mesh products.

4
5 26. The Defendants have marketed and sold the Defendants' Pelvic Mesh Product
6 to the medical community at large and patients through carefully planned, multifaceted
7 marketing campaigns and strategies. These campaigns and strategies include, but are not
8 limited to direct to consumer advertising, aggressive marketing to health care providers at
9 medical conferences, hospitals, private offices, and include the provision of valuable
10 consideration and benefits to health care providers. Also utilized are documents, brochures,
11 websites, and telephone information lines, offering exaggerated and misleading expectations
12 as to the safety and utility of the Defendants' Pelvic Mesh Product.
13

14 27. Contrary to the Defendants' representations and marketing to the medical
15 community and to the patients themselves, the Defendants' Pelvic Mesh Product has high
16 failure, injury, and complication rates, fails to perform as intended, requires frequent and
17 often debilitating re-operations, and has caused severe and irreversible injuries, conditions,
18 and damage to a significant number of women, including the Plaintiff.
19

20 28. The Defendants have consistently underreported and withheld information
21 about the propensity of Defendants' Pelvic Mesh Product to fail and cause injury and
22 complications, and have misrepresented the efficacy and safety of the Product, through
23 various means and media, actively and intentionally misleading the FDA, the medical
24 community, patients, and the public at large.
25

26 29. Defendants have known and continue to know that their disclosures to the
27 FDA were and are incomplete and misleading; and that the Defendants' Pelvic Mesh Product
28

1 was and is causing numerous patients' severe injuries and complications. The Defendants
2 suppressed this information and failed to accurately and completely disseminate or share this
3 and other critical information with the FDA, health care providers, or the patients. As a result,
4 the Defendants actively and intentionally misled and continue to mislead the public, including
5 the medical community, health care providers and patients, into believing that the Defendants'
6 Pelvic Mesh Product was and is safe and effective, leading to the prescription for and
7 implantation of the Pelvic Mesh Product into the Plaintiff.
8

9 30. Defendants failed to perform or rely on proper and adequate testing and
10 research in order to determine and evaluate the risks and benefits of the Defendants' Pelvic
11 Mesh Product.
12

13 31. Defendants failed to design and establish a safe, effective procedure for
14 removal of the Defendants' Pelvic Mesh Product; therefore, in the event of a failure, injury,
15 or complications it is impossible to easily and safely remove the Defendants' Pelvic Mesh
16 Product.
17

18 32. Feasible and suitable alternative designs as well as suitable alternative
19 procedures and instruments for implantation and treatment of stress urinary incontinence,
20 pelvic organ prolapse, and similar other conditions have existed at all times relevant as
21 compared to the Defendants' Pelvic Mesh Product.
22

23 33. The Defendants' Pelvic Mesh Product was at all times utilized and implanted
24 in a manner foreseeable to the Defendants.

25 34. The Defendants have at all times provided incomplete, insufficient, and
26 misleading training and information to physicians, in order to increase the number of
27 physicians utilizing the Defendants' Pelvic Mesh Product, and thus increase the sales of the
28

1 Product, and also leading to the dissemination of inadequate and misleading information to
2 patients, including Plaintiff.

3 35. The Pelvic Mesh Product implanted into the Plaintiff was in the same or
4 substantially similar condition as it was when it left the possession of Defendants, and in the
5 condition directed by and expected by the Defendants.
6

7 36. The injuries, conditions, and complications suffered due to Defendants' Pelvic
8 Mesh Product include but are not limited to mesh erosion, mesh contraction, infection, fistula,
9 inflammation, scar tissue, organ perforation, dyspareunia, blood loss, neuropathic and other
10 acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage,
11 pelvic pain, urinary and fecal incontinence, prolapse of organs, and in many cases the women
12 have been forced to undergo intensive medical treatment, including but not limited to
13 operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue,
14 and nerve damage, the use of pain control and other medications, injections into various areas
15 of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia,
16 and injuries to Plaintiff's intimate partners.
17

18 37. Despite Defendants' knowledge of these catastrophic injuries, conditions, and
19 complications caused by their Pelvic Mesh Product, the Defendants have, and continue to
20 manufacture, market, and sell the Product, while continuing to fail to adequately warn, label,
21 instruct, and disseminate information with regard to the Defendants' Pelvic Mesh Product,
22 both prior to and after the marketing and sale of the Product.
23

24
25 **VI. FIRST CAUSE OF ACTION**
26 **WASHINGTON PRODUCT LIABILITY ACT**

27 38. Plaintiffs incorporate by reference all prior paragraphs of this Complaint as if
28

1 fully set forth herein and further alleges as follows:

2 39. At all times relevant to this litigation, Defendants engaged in the business of
3 testing, developing, designing, manufacturing, marketing, selling, distributing, and
4 promoting its medical device products.
5

6 40. At all times relevant to this litigation, Defendants designed, researched,
7 developed, manufactured, produced, tested, assembled, labeled, advertised, promoted,
8 marketed, sold, and distributed the medical device used by Plaintiff as described above.

9 41. At all times relevant to this litigation, Defendants' medical device was
10 expected to reach and did reach the intended consumers, handlers, and users or other persons
11 coming into contact with these products in Washington and throughout the United States,
12 including Plaintiff, without substantial change in their condition as designed, manufactured,
13 sold, distributed, labeled, and marketed by Defendants.
14

15 42. In violation of the Washington Products Liability Act ("WPLA"), RCW 7.72,
16 et seq., at all times relevant to this action, at the time Defendants' medical device left control
17 of Defendants, it was defective and not reasonably safe. These defects include, but are not
18 limited to, the following:
19

- 20 a) Defendants are strictly liable for Plaintiff's injuries and damages
21 because at the time of manufacture, and at the time Defendants'
22 medical device left control of Defendants, the likelihood that the
23 medical device would cause injury or damage similar to that
24 suffered by Plaintiff, and the seriousness of such injury or damage
25 had been known by Defendants and outweighed the burden on
26 Defendants to design a product that would have prevented Plaintiff's
27 injuries and damages and outweighed the adverse effect that an
28 alternative design that was practical and feasible would have on the
usefulness of the subject product.
- b) Defendants' medical device is unsafe to an extent beyond that which
would be contemplated by an ordinary consumer.

- 1
- 2 c) The medical device manufactured and/or supplied by Defendants
- 3 was defective in design in that, an alternative design and/or
- 4 formulation exists that would prevent severe and permanent injury.
- 5 Indeed, at the time that Defendants designed their medical device,
- 6 the state of the industry's scientific knowledge was such that a less
- 7 risky design or formulation was attainable.
- 8
- 9 d) The medical device was not reasonably safe in design under the
- 10 WPLA.
- 11
- 12 e) The medical device manufactured and/or supplied by Defendants
- 13 was not reasonably safe because Defendants did not provide an
- 14 adequate warning or instruction about the product. At the time the
- 15 medical device left Defendants' control, the device possessed
- 16 dangerous characteristics and Defendants failed to use reasonable
- 17 care to provide an adequate warning of such characteristics and their
- 18 danger to users and handlers of the product. The medical device is
- 19 not safe and cause severe and permanent injuries. The medical
- 20 device was not reasonably safe because the warning was inadequate,
- 21 and Defendants could have provided adequate warnings or
- 22 instructions.
- 23
- 24 f) The medical device that was manufactured and/or supplied by
- 25 Defendants was not reasonably safe because adequate warnings or
- 26 manufacturer instructions were not provided after the medical
- 27 device was manufactured and when Defendants learned of, or
- 28 should have learned of, the dangers connected with the medical
- device.
- g) The medical device manufactured and/or supplied by Defendants
- was not reasonably safe because it did not conform to an express
- warranty made by Defendants regarding the product's safety and
- fitness for use. Defendants expressly warranted that the medical
- device was safe and fit for their intended purposes, that it was of
- merchantable quality, that it was not produce any dangerous side
- effects, that they were adequately tested, and that the device was
- safe to human health and the environment, and effective, fit, and
- proper for its intended use. Defendants did not disclose the material
- risks that its medical device could cause severe and permanent
- injury. Defendants' express warranty induced Plaintiff to use the
- device, and Plaintiff's damages were proximately caused because
- Defendants' express warranty was untrue. The mesh product was
- not reasonably safe because of nonconformity to express warranty
- under the WPLA.

1
2 43. As a direct and proximate result of Defendants placing their its defective
3 medical device into the stream of commerce, Plaintiff suffered grave injuries, and endured
4 physical and emotional pain and discomfort, as well as economic hardship, including
5 considerable financial expenses for medical care and treatment and other damages further
6 discussed in herein.

7
8 WHEREFORE, Plaintiff demands judgment against Defendants, and each of them,
9 individually, jointly, severally and in the alternative, and request compensatory damages,
10 punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief
11 as the Court deems equitable and just.

12
13 **VII. SECOND CAUSE OF ACTION**
VIOLATION OF THE WASHINGTON CONSUMER PROTECTION ACT

14
15 44. Plaintiff realleges and incorporates by reference every allegation of this
16 Complaint as if each were set forth fully and completely herein.

17 45. Plaintiff purchased and used the Defendants' Pelvic Mesh Product primarily
18 for personal use and thereby suffered ascertainable losses as a result of Defendants' actions
19 in violation of the consumer protection laws.

20 46. Had Defendants not engaged in the deceptive conduct described herein,
21 Plaintiff would not have purchased and/or paid for the Defendants' Pelvic Mesh Product, and
22 would not have incurred related medical costs and injury.

23
24 47. Defendants engaged in wrongful conduct while at the same time obtaining,
25 under false pretenses, moneys from Plaintiff for the Pelvic Mesh Product that would not have
26 been paid had Defendants not engaged in unfair and deceptive conduct.
27
28

- a) Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:
- b) Representing that goods or services has characteristics, ingredients, uses benefits or quantities that they do not have;
- c) Advertising goods or services with the intent not to sell them as advertised; and,
- d) Engaging in fraudulent or deceptive conduct that creates a likelihood of confusion or misunderstanding.

48. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Defendants' Pelvic Mesh Product. Each aspect of Defendants' conduct combined to artificially create sales of the Defendants' Pelvic Mesh Product.

49. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of the Defendants' Pelvic Mesh Product.

50. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the Product, and would not have incurred related medical costs.

51. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of the state consumer protection statutes listed.

52. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of state

1 consumer protection statutes, as listed below.

2 53. Defendants have engaged in unfair competition or unfair or deceptive acts or
3 trade practices or have made false representations.

4 54. Under applicable state statutes enacted to protect consumers against unfair,
5 deceptive, fraudulent and unconscionable trade and business practices and false advertising,
6 Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to
7 liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer
8 sales practices.

9 55. Defendants violated the statutes that were enacted in these states to protect
10 consumers against unfair, deceptive, fraudulent and unconscionable trade and business
11 practices and false advertising, by knowingly and falsely representing that the Defendants'
12 Pelvic Mesh Product was fit to be used for the purpose for which it was intended, when in
13 fact it was defective and dangerous, and by other acts alleged herein. These representations
14 were made in marketing and promotional materials.

15 56. The actions and omissions of Defendants alleged herein are uncured or
16 incurable deceptive acts under the statutes enacted in the states to protect consumers against
17 unfair, deceptive, fraudulent and unconscionable trade and business practices and false
18 advertising.

19 57. Defendants had actual knowledge of the defective and dangerous condition of
20 the Defendants' Pelvic Mesh Product and failed to take any action to cure such defective and
21 dangerous conditions.

22 58. Plaintiff and the medical community relied upon Defendants'
23 misrepresentations and omissions in determining which product and/or procedure to undergo
24

1 and/or perform (if any).

2 59. Defendants' deceptive, unconscionable or fraudulent representations and
3 material omissions to patients, physicians and consumers, constituted unfair and deceptive
4 acts and practices.
5

6 60. By reason of the unlawful acts engaged in by Defendants, and as a direct and
7 proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

8 61. As a direct and proximate result of Defendants' violations of the states'
9 consumer protection laws, Plaintiff has sustained economic losses and other damages and is
10 entitled to statutory and compensatory, damages in an amount to be proven at trial.
11

12 WHEREFORE, Plaintiff demands judgment against Defendants, and each of them,
13 individually, jointly, severally and in the alternative, and request restitution and disgorgement
14 of profits, together with interest, cost of suit, attorneys' fees, and all such other and further
15 relief as this Court deems just and proper.
16

17 **VIII. PUNITIVE DAMAGES**

18 62. Plaintiff realleges and incorporates by reference every allegation of this
19 Complaint as if each were set forth fully and completely herein.

20 63. The wrongs done by Defendants were aggravated by the kind of malice, fraud,
21 and grossly negligent disregard for the rights of others, the public, and Plaintiff for which the
22 law would allow, and which Plaintiff will seek at the appropriate time under governing law
23 for the imposition of exemplary damages, in that Defendants' conduct, including the failure
24 to comply with applicable Federal standards: was specifically intended to cause substantial
25 injury to Plaintiff; or when viewed objectively from Defendants' standpoint at the time of the
26 conduct, involved an extreme degree of risk, considering the probability and magnitude of
27
28

1 the potential harm to others, and Defendants were actually, subjectively aware of the risk
2 involved, but nevertheless proceeded with conscious indifference to the rights, safety, or
3 welfare of others; or included a material representation that was false, with Defendants,
4 knowing that it was false or with reckless disregard as to its truth and as a positive assertion,
5 with the intent that the representation is acted on by Plaintiff.
6

7 64. Plaintiff relied on the representation and suffered injury as a proximate result
8 of this reliance.

9 65. Plaintiff therefore will seek to assert claims for exemplary damages at the
10 appropriate time under governing law in an amount within the jurisdictional limits of the
11 Court.
12

13 66. Plaintiff also alleges that the acts and omissions of named Defendants,
14 whether taken singularly or in combination with others, constitute gross negligence that
15 proximately caused the injuries to Plaintiff. In that regard, Plaintiff will seek exemplary
16 damages in an amount that would punish Defendants for their conduct and which would deter
17 other manufacturers from engaging in such misconduct in the future.
18

19 WHEREFORE, Plaintiff demands judgment against Defendants, and each of them,
20 individually, jointly, severally and in the alternative, and request compensatory damages,
21 together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems
22 equitable and just.
23

24 **IX. PRAYER FOR RELIEF**

25 WHEREFORE, Plaintiff demands judgment against Defendants, and each of them,
26 individually, jointly and severally and requests compensatory damages, together with
27 interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and
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proper as well as:

- A. All general, statutory, and compensatory damages, in excess of the amount required for federal diversity jurisdiction, and in an amount to fully compensate Plaintiff for all injuries and damages, both past and present;
- B. All special and economic damages, in excess of the amount required for federal diversity jurisdiction and in an amount to fully compensate Plaintiff for all of her injuries and damages, pain and suffering;
- C. Attorneys' fees, expenses, and costs of this action;
- D. Double or triple damages as allowed by law;
- E. Punitive and/or exemplary damages;
- F. Pre-judgment and post-judgment interest in the maximum amount allowed by law; and
- G. Such further relief as this Court deems necessary, just, and proper.

X. DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all issues so triable.

Dated this 7th day of July, 2020.

CORRIE YACKULIC LAW FIRM, PLLC

/s/ Corrie J. Yackulic

Corrie J. Yackulic, WSBA No. 16063
110 Prefontaine Place South, Suite 304
Seattle, Washington 98104
Tel. 206-787-1915
Fax. 206-299-9725
Corrie@cjylaw.com

/s/ Dana Lizik

Dana Lizik
JOHNSON LAW GROUP
Texas State Bar No. 24098007
2925 Richmond Avenue, Suite 1700
Houston, Texas 77098

(713) 626-9336
(713) 583-9460 (facsimile)
Email: dlizik@johnsonlawgroup.com
[Applying *pro hac vice*]

Attorneys for Plaintiff